

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12572



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

CFSAW Page 1 of 1

Form Approved: OMB No. 0910-0201 Expires 12/31/94
See OMB statement on reverse

FDA Use Only	H Pad
Triage unit sequence #	69735
	12572

A. Patient information

1. Patient identifier [redacted] In confidence	2. Age at time of event: or <u>adult</u> Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	
3. Date of event (mo/day/yr) <u>8/18/97</u>	4. Date of this report (mo/day/yr) <u>9/10/97</u>

5. Describe event or problem

ingestion of 12 "stackers" lead to tachycardia → admission to hospital.

Stackers sold through [redacted], a store located on [redacted] in [redacted].

Product contains unknown amount of ephedrine. The poison center called the store & they denied selling the product. Physician called store & was told the product contained ephedrine, but did not disclose the amount.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

obesity, other unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 <u>Stackers</u>	
#2	
2. Dose, frequency & route used	
#1 <u>12 tabs x1 ingestion</u>	3. Therapy dates (if unknown, give duration) (mo/yr) (or best estimate)
#2	
4. Diagnosis for use (indication)	
#1 <u>obesity/wt loss</u>	5. Event abated after use stopped or dose reduced
#2	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	
#1	7. Exp. date (if known)
#2	
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # (for product problems only)	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
<u>unknown</u>	

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	
4. Operator of device	
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other: _____	
5. Expiration date (mo/day/yr)	
6. model # <u>SEP 10 1997</u>	
7. If implanted, give date (mo/day/yr)	
8. If explanted, give date (mo/day/yr)	
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
<u>000001</u>	

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
[redacted]			
2. Health professional?	3. Occupation	4. Also reported to	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	<u>Pharmacist</u>	<input type="checkbox"/> manufacturer	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		<input type="checkbox"/> user facility	
		<input type="checkbox"/> distributor	



Mail to: MEDWATCH
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or FAX to:
1-800-FDA-0178